

## **REMARKS**

### **A. Ambiguity in Office Action**

In the December 28, 2004 Office Action, page 2, paragraph 2, claim 20 is rejected. However, in paragraph 4, claim 20 is indicated as allowable if written in independent format. The Office Action Summary (paragraphs 6 and 7) does not contain such an ambiguity. It is believed this ambiguity is made moot by the foregoing amendments.

### **B. Allowable Claims**

Claims 2, 7, 11, 13, 17, 18, 21 and 22 are amended to be presented in independent format with all limitations of their base claim and any intervening claims. Claims 3 – 6, 8, 9, 12, 23 and 24 depend from these now allowable claims. Therefore, claims 2 – 9, 11 – 13, 17, 18 and 21 – 24 are submitted as allowable for the reasons given in paragraph 4, page 2 of the Office Action. Claims 3 and 4 are amended to add a proper antecedent basis for a claim term.

### **C. Rejected Claims**

#### **1. The Cited Art**

Independent claims 1 and 19 were rejected as anticipated by Hart (US 5,957,133). Independent claims 1, 10, 15 and 19 were rejected as anticipated by Straith (US 4,553,540). Neither of Hart or Straith show or suggest any method or structure for altering airway geometry in any manner which survives removal of the devices taught in Hart and Straith.

Hart describes a device which does not compress tissue or enlarge the airway at all. In Hart, the inventor is attempting to draw the soft palate 48 away from posterior laryngeal wall 43 during inhalation. The intent is for the patient to breath by drawing air through the nose. The invention is to apply suction to the soft palate through opening 24. This suction urges the soft palate 48 to move from a blocking position (48' in Fig. 2) to a position with the palate urged against the hollow body (this position is shown as 48'' in Fig. 2). In this position, the palate 48 does not block airflow from the nose. This description of operation is found in Hart, column 3, lines 51 – 65.

In Hart, there is no compression of soft tissue and no therapeutic benefit after the apparatus 10 is withdrawn from mouth. Therapy is only provided during periods in which the oral appliance 10 is being used.

Straith describes a type of well-known intubation devices to maintain an open airway during surgery when a patient is under anesthetic (Straith, col. 1, ln. 9). Straith is attempting to overcome prior art problems in which the tongue displaces the intubation device (Straith, col. 1, ln. 38). There is no suggestion of a treatment for snoring and sleep apnea. The device 10 has a hinged clamping member 32 which pushes the tongue away from the back of the throat during use (illustrated in Fig. 2). Once the device 10 is removed, there is no lasting re-shaping of any airway.

## **2. Amendments to Define over the Cited Art**

The remaining independent claims are all amended to recite method steps or apparatus structure clarifying that the present invention (1) expands the pharyngeal airway and (2) maintains the expansion after removal of the expanding member. So amended, the claims distinguish over Hart and Straith since those prior art teachings do not show or suggest any maintenance of the enlarged airway after removal of the devices taught in those patents. Further, the claims recite treating the tissue to retain patency which would distinguish over any residual dilatation of the simple mechanical treatments of the prior art.

- Claim 1 is amended to add the method step of “treating said portions to retain said portions in said outwardly displaced position following deactivation of said expander member”.
- Claim 10 and 15 are amended to add the method step of “said stabilizing include treating said portion to resist inward collapse independent of a mechanical force acting against an external tissue of said pharyngeal wall within said airway”.
- Claim 19 is amended to add the structure of “an applicator to treat said portions in said outwardly displaced position with a treatment to retain said portions in said outwardly displaced position following deactivation of said expander member”.

The cited art does not show or suggests these method steps or structure. The prior art alters airway shape only while the apparatus remains in the airway. This is undesirable for comfortable sleep. The present invention describes a treatment method and apparatus which

applies a device in the airway against the tissue only during treatment with the benefits of altered airway tissue lasting after removal of the device. Therefore, the amended claims are submitted as allowable. Claims not otherwise discussed in this Amendment depend from amended claims and are submitted as allowable for dependency from allowable claims together with the added limitations of the dependent claims.

Applicant respectfully submits this application is now in condition for allowance.  
Reconsideration and Notice of Allowance are solicited.

Respectfully submitted,

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